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IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TEXAS  
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA,	.	
<i>EX REL,</i>	.	
AND PETER HUESEMAN,	.	
	.	
PLAINTIFFS,	.	
vs.	.	DOCKET NO. SA:14-CV-212-XR
	.	
PROFESSIONAL COMPOUNDING	.	
CENTERS OF AMERICA, INC.,	.	
	.	
DEFENDANT.	.	

TRANSCRIPT OF MOTION TO DISMISS PROCEEDINGS  
BEFORE THE HONORABLE XAVIER RODRIGUEZ  
UNITED STATES DISTRICT JUDGE  
JUNE 16, 2022

APPEARANCES:	
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ON BEHALF OF RELATOR:	GLENN GROSSENBACHER, ESQUIRE LAW OFFICE OF GLENN GROSSENBACHER 24165 IH-10 W SUITE 217766 SAN ANTONIO TX 78257-1160
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1 ON BEHALF OF  
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9 REPORTED BY:

GIGI SIMCOX, RMR, CRR  
OFFICIAL COURT REPORTER  
UNITED STATES DISTRICT COURT  
SAN ANTONIO, TEXAS

1       (San Antonio, Texas; June 16, 2022, at 10:30 a.m., via  
2       Zoom videoconference.)

3               THE COURT: Let's turn to 14 civil 212, U.S.A., ex  
4       rel Hueseman versus Professional Compounding Centers of  
5       America.

6               Who do we have for the plaintiff?

7               Do I have somebody?

8               (Crosstalk)

9               MR. GROSSENBACHER: Yes, Glenn Grossenbacher for  
10       relator.

11              THE COURT: Thank you.

12              And do we have anybody from the government?

13              MR. DECK: Yeah. Sorry, Your Honor. I was on mute.

14              This is John Deck for the United States. I'm also  
15       joined by my colleagues, Sanjay Bhambhani, Nathan Green, and  
16       Danielle (inaudible).

17              THE COURT: Thank you.

18              And for PCCA?

19              MR. BURBA: Yes, Your Honor. Tony Burba for PCCA.

20              And also joining on the call are my partners, Mike  
21       Battle, David Frazee, and Alicia Barrs. We also have for  
22       observation, representatives from our client, Mr. Marc DuPont  
23       and Fabian Zaccardo.

24              THE COURT: Thank you.

25              So we have this False Claims Act case, and I'll start

1 I guess with the plaintiff, the relator and/or the government  
2 to help me understand this, but as best I can figure out, PCCA  
3 makes ingredients that they sell to pharmacies and then the  
4 pharmacies use these ingredients to make compound drugs.

5 And then when they make the compound drug they bill  
6 that to TRICARE, and when they bill that to TRICARE they have  
7 to identify each of the ingredients in that compound  
8 medication. And what they are doing there is billing to  
9 TRICARE the ingredients based upon an average wholesale price  
10 that PCCA gave them.

11 And the allegation is that -- and I'll just make up  
12 numbers, just for the sake of a hypothetical -- they will bill  
13 TRICARE \$100 for this ingredient, when PCCA only charged them  
14 \$1. And of course, I'm just making up numbers here.

15 Do I have the theory of this case right?

16 I'll start with the relator.

17 MR. GROSSENBACHER: Yes, Your Honor, but I'll defer  
18 to the government and concur with our arguments laid out in  
19 the motion -- response to the motion to dismiss. That's  
20 exactly what the allegation is, as you described it.

21 THE COURT: And so if that's right then, and I'm  
22 trying to understand PCCA's motion to dismiss, PCCA is giving  
23 the pharmacy an AWP that it uses, and my understanding --  
24 someone correct me if I'm wrong -- when TRICARE receives that  
25 bill, what they are doing is they are going to some third

1 party, and I'm not sure where they go look at this, and they  
2 look to see, okay, how much is the AWP. And PCCA is also  
3 posting on that third site that number that's higher than what  
4 the actual billing was.

5 Am I right on that?

6 And let me hear from the government.

7 MR. DECK: Right, Your Honor. You are right in your  
8 explanation.

9 What I would point out, although it's not terribly  
10 relevant is that PCCA doesn't actually manufacture these  
11 ingredients. As I understand it, they purchase them from  
12 third parties and then they repackage them and they sell them  
13 to their customers.

14 THE COURT: Okay.

15 MR. DECK: But you are right, they set the AWP and  
16 they send it to these pricing compendia that are, you know,  
17 standard pricing catalogs in the industry and the government  
18 will reimburse the drug on one of three metrics, whichever is  
19 lower, AWP, the price to the pharmacy, or the usual and  
20 customary price, which is basically what a cash purchaser  
21 would pay.

22 And the allegation here is that during the relevant  
23 period the government was paying the AWP, in part because PCCA  
24 customers, at PCCA's urging, were hiding their actual costs  
25 and then manipulating the usual and customary costs so that

1 the government would pay the AWP.

2 THE COURT: And what's the theory of the government?  
3 How much money do you think was overpaid because of this  
4 practice?

5 MR. DECK: In the complaint we stated that the  
6 government overpaid hundreds of millions of dollars for PCCA's  
7 ingredients alone. Although it's not pled in the complaint,  
8 we think that number is a little like under a billion dollars  
9 total, for PCCA's ingredients alone.

10 THE COURT: Thank you.

11 So let me turn to PCCA and let me allow you to make  
12 any arguments you have on your motion to dismiss.

13 MR. BURBA: Thank you, Your Honor.

14 I would first say that if the government's position  
15 is now that single damages are approaching a billion dollars,  
16 that would be the first time that's been disclosed to us. I  
17 think the single damages number that have been presented to us  
18 have been substantially lower than that number.

19 Our position is that this is not an FCA case and we  
20 don't think that there are any disputed facts that the Court  
21 needs to resolve to make that determination.

22 This case targets a company that does no business  
23 with the government, never has. A company that's never made  
24 or sold anything that the government pays for.

25 They have never submitted any kind of claim for

1 payment, directly or indirectly to the government. They have  
2 never had any kind of contractual relationship with the  
3 government.

4           They have never received payment from the government,  
5 and they are alleged to have reported to nongovernmental third  
6 parties AWP's that the government now says were inflated,  
7 despite the fact that the term "AWP" still remains undefined  
8 by the government, even in their most recent filing of their  
9 response or in their complaint.

10           The government says that the fraud is actionable  
11 under the False Claims Act, even though they don't allege that  
12 PCCA was subject to any of the regulatory or sub-regulatory  
13 guidance that they describe in the complaint. And the  
14 government doesn't even allege in their complaint that PCCA  
15 was aware of any of that guidance, and has now suggested in  
16 their response that they don't need to show that.

17           The government is essentially asking the Court to  
18 infer the existence of conduct subject to the False Claims Act  
19 because it says so. It's asking the Court to draw inferences  
20 in its favor based on little more than the use of the words  
21 "fraudulent" and "false" in the complaint.

22           In fact, under the law in this district, falsity  
23 requires an objective standard by which the Court and the  
24 parties can measure AWP. And the government points to no  
25 authority suggesting otherwise, other than a recent criminal

1 case under a different statute.

2           Moreover, the government points to no objective  
3 measure of AWP to which PCCA could have looked at the time  
4 that they are alleged to have committed the fraud, nor even  
5 any objective standard that we could look to now in defending  
6 ourselves.

7           The government seeks to coddle together legal support  
8 for its theory of materiality and falsity that's wholly  
9 inapposite. They talk about state Supreme Court cases and  
10 out-of-circuit cases that examine AWP, not in the context of  
11 materiality and the False Claims Act, but in the context of  
12 state laws, and in most cases, state consumer fraud laws. And  
13 those cases were all dealing with the issue of AWP prior to  
14 the Supreme Court's decision in *Escobar*.

15           By reading of the 2009 First Circuit opinion that the  
16 court — or that the government cites in their response, I  
17 think is instructive. In that case, the Court was not looking  
18 at materiality as defined under the state — or under the  
19 False Claims Act, even at that time.

20           It was rather examining AWP as it related to a state  
21 consumer fraud action. And in fact, that court held, and I  
22 will -- and I can quote from that opinion, that this case --  
23 paraphrasing -- this case does not involve any  
24 misrepresentations to Medicare.

25           So this case is not a False Claims Act case. It's a



1 theory in search of facts and law to support it, and the  
2 government's essentially trying to convince the Court here  
3 that the old hits are the best, but their case is just a cover  
4 band and the old hits don't possess any magic to convert their  
5 baseless claims into a False Claims Act case.

6           The conduct of TRICARE in this case obviates any  
7 proof of falsity, knowledge, causation, or materiality. The  
8 government is essentially looking to shift blame for an  
9 alleged loss that was caused by its own mistakes.

10           The government could have stopped the reimbursement  
11 of these claims for compounds based on AWP at any time, simply  
12 by following its own regulations. TRICARE has admitted in the  
13 GAO report attached to our motion to dismiss that it knew of  
14 these issues since at least July of 2012 and did nothing for  
15 three years.

16           Even after the government alleges that TRICARE took  
17 corrective action on May 1st of 2015, Exhibit 22 to the  
18 government's complaint shows that TRICARE kept making payments  
19 on claims which the government now takes issue with. Twelve  
20 of the government's 325 handpicked representative claims in  
21 Exhibit 22 postdate the alleged corrective action taken by  
22 TRICARE.

23           The Court should not allow the government to shift  
24 the blame for its own mistakes to a company that had no reason  
25 to believe it was beholden to the regulations that the

1 government itself was violating.

2 In closing, I would point the Court to the *Escobar*  
3 opinion, pages 195 and 196 in the Westlaw citation. We  
4 reference in our motion to dismiss and our reply that the  
5 government here, if its theory is to be accepted, is expanding  
6 the False Claims Act well beyond the boundaries intended by  
7 Congress, and well beyond the parameters that the court -- the  
8 Supreme Court has set forth.

9 In *Escobar*, the government's theory of materiality  
10 was that any violation of any regulatory requirement that  
11 might allow the government to deny payment was material.

12 That rings of the government's argument here, which  
13 is that because the government chose to consider information  
14 outside the context of its own regulations and rely on that  
15 information, that somehow that information was material.

16 But Justice Thomas, in the *Escobar* opinion, expressed  
17 his concern about this theory and the breadth of it and that  
18 the government could, for instance, in its Medicare contracts  
19 could end a requirement that all providers use American-made  
20 staplers, and that the use of a foreign-made stapler, even  
21 though it's wholly irrelevant to the service the government is  
22 seeking, could cause substantial liability under the False  
23 Claims Act case.

24 Our position is that here the government is not going  
25 after providers who used a noncompliant stapler, they are

1 going after the stapler company, and we believe that their  
2 theory is well in excess of what the False Claims Act is  
3 contemplated to cover.

4 And in the absence of having identified any product  
5 controlled, sold, or otherwise relevant to PCCA's business,  
6 that the government has ever paid for, it also falls short of  
7 the requirements of the antikickback statute.

8 THE COURT: Well, I was going to turn to that. What  
9 of the antikickback?

10 I mean, the complaint is stating that you-all had  
11 your customers, these pharmacy companies, pay to belong to  
12 some kind of like a membership club, and the allegations in  
13 the complaint are you were telling your members/pharmacies not  
14 to be disclosing to TRICARE the actual amount you were  
15 charging them, and so these -- I'll ask the government here in  
16 a little bit why we aren't going after the pharmacy companies,  
17 I agree with that comment, but you guys are receiving monies  
18 in exchange for this, so why isn't the complaint sufficient  
19 for the antikickback statute?

20 MR. BURBA: Well, I would suggest, Your Honor, that I  
21 personally have received a gift basket at Christmas from  
22 e-Discovery companies I use, but I don't think those  
23 e-Discovery companies would consider themselves covered by the  
24 False Claims Act just because they sent a lawyer who  
25 represents health care companies a basket.

1           And our position here is the issue of remuneration is  
2 irrelevant because the products at issue do not fit within the  
3 parameters of the antikickback statute. We don't sell  
4 anything that would pull us into the antikickback statute.

5           We sell something that may be tangential to something  
6 that the government paid for, frankly something the government  
7 paid for that it shouldn't have, but no pharmacy has ever  
8 submitted a claim for PCCA's products. They have submitted  
9 claims for compounded medications --

10           THE COURT: Well, isn't that parsing things -- that  
11 seems to be parsing things way too thin. Your ingredients are  
12 going into the compound pharmaceutical, correct?

13           MR. BURBA: Correct.

14           THE COURT: Yeah. Let's hear from the government.  
15 What's your response to all this?

16           MR. DECK: Your Honor, I'm not going to try to make a  
17 point-by-point refutation of what Mr. Burba just said.

18           I think the complaint, which is nearly 50 pages,  
19 sufficiently pleads all the claims here. And I think our  
20 briefing, which was, you know, over 60 pages, went point by  
21 point to say why PCCA is wrong in saying this case warrants  
22 dismissal.

23           I do want to focus in on three arguments that PCCA  
24 makes. The first is that TRICARE somehow didn't follow its  
25 regulation because it supposedly didn't cover the ingredients.

1 To start, the allegations in the complaint, which the Court  
2 must accept as true at this point, contradicts its contention.

3           They allege that PCCA knew TRICARE reimbursed its  
4 customers. In fact, it sought to delay changes in TRICARE's  
5 policies so that the reimbursements would continue. And then  
6 once TRICARE stopped paying, this is alleged in the complaint  
7 too, its president lamented because its purchases -- their  
8 customers' purchases declined quickly and sharply.

9           And regardless, none of the elements of the AKS or  
10 the FCA depend on TRICARE's coverage or authority to  
11 reimburse. And any negligence, or error, or mistake by the  
12 government can't justify PCCA's fraud.

13           The second argument is that PCCA contends that its  
14 AWP can't be false because there is no definition. This has  
15 been repeatedly rejected by courts. Mr. Burba cited the First  
16 Circuit opinion, which we also cite, and it says that the  
17 government use of AWP does not grant the pharmaceutical  
18 industry, quote, "unfettered discretion to report drug prices  
19 that bear no relation to products actual prices."

20           And what the Court was doing there is that they were  
21 affirming the trial court's finding that if AWPs in that case,  
22 for a cancer drug, were more than 30 percent above the  
23 acquisition cost for that drug, then they were false and  
24 inflated.

25           Here, we have AWPs that were inflated between 1300

1 and 56,000 percent. These AWP's were no relation to anything,  
2 except profits for PCCA and its customers. And the government  
3 contends are false by any measure.

4           The third and final argument I want to focus in on is  
5 this claim that the government continued to pay after it had  
6 knowledge of wrongdoing. Again, this is an incorrect  
7 assertion given the facts alleged which the Court must accept  
8 as true.

9           The government acted here when it had sufficient  
10 knowledge of fraud in November 2014, which is just eight  
11 months after the relator filed this lawsuit notifying the  
12 government of its allegations. The government acted to  
13 curtail payment by recommending a control, prior authorization  
14 for these claims.

15           Then in May 2015, after, you know, the required  
16 administrative processes, the government enacted these  
17 controls, and the number of claims declined sharply and PCCA's  
18 sells plummeted.

19           What PCCA appears to argue is that if the government  
20 generally knows about fraud, here AWP inflation, somewhere in  
21 the pharmaceutical industry, then that's sufficient notice and  
22 it precludes any prosecution.

23           Now, that position is absurd because the government  
24 knows about all sorts of fraud generally. If that was  
25 sufficient, then the government even couldn't use the FCA and

1 the AKS at all.

2           The position is also inconsistent with the law. What  
3 *Escobar* says is that the government must have actual knowledge  
4 that certain requirements were violated. General knowledge is  
5 not enough.

6           And regardless, you know, knowledge and then  
7 continued payment is only one nondispositive factor under  
8 *Escobar*, and it only goes to one element of the FCA.

9           In *Harman*, the case from the Fifth Circuit, has said  
10 that no factor, including government knowledge, is  
11 dispositive.

12           Mr. Burba says that the government knew about, I  
13 guess, the fraud, the specific fraud here, since July of 2015.  
14 Now, the document he cites is the October 24 GOA report. I  
15 think it's Exhibit 1 to their motion to dismiss.

16           Now, that document doesn't say that the government  
17 knew about the inflation here. It says, quote, "Since  
18 July 2012 TRICARE has continued to pay for compound drug  
19 prescriptions containing bulk drug substances." That's not  
20 saying the government knew about the fraud here.

21           Moreover, the document does not state that PCCA was  
22 inflating the AWP, the extent of the inflation, or the  
23 marketing of the spread.

24           And even if the government knew about the inflation  
25 in October 2014, or even July 2012, the government here acted

1 in November of 2014 to stop payment. And as this Court has  
2 observed in the PVA case, quote, "Health care administration  
3 is complicated. The government does not enjoy the luxury of  
4 refusing to reimburse health care the moment it suspects there  
5 may be wrongdoing."

6 You know, TRICARE is a gigantic program. It ensures  
7 millions of people. Many of them are active military. The  
8 government can't just, at the drop of a hat, stop payment.  
9 And it's particularly rich for PCCA to be making this argument  
10 when it's alleged in the complaint that at the time that  
11 TRICARE is considering these changes, it was actively trying  
12 to stop TRICARE from making the changes.

13 What PCCA really disputes here is what the government  
14 knew and when it knew it. Now, if these are matters at all,  
15 they are matters of proof. They are not legal grounds for  
16 dismissal. So we think that all of PCCA's arguments fail and  
17 we think the motion should be dismissed in its entirety.

18 And I mean, I'll take any questions you have, Your  
19 Honor, on those issues or on anything else.

20 THE COURT: So let's act under the assumption that  
21 the motion to dismiss is denied. So I am curious about your  
22 calculations here and how we got to a billion dollars. This  
23 is probably for another day, but I want to tee this up so  
24 everybody is talking here amongst themselves if this is  
25 possible.



1           So you know, the individuals or the companies that  
2 made most of this money off TRICARE seem to be the pharmacies.  
3 So how is it that we are going under this theory that all that  
4 amount of loss is attributable to this defendant? Under what  
5 theory do you attribute the entirety of the loss to this  
6 defendant?

7           MR. DECK: Well, I mean, under the AKS, any claim  
8 tainted by a kickback is in the damages, like you get the  
9 entire claim.

10          THE COURT: But is it that amount?

11          MR. DECK: And so —

12          THE COURT: Is that amount calculated by how much it  
13 received, not the total amounts paid?

14          MR. DECK: Yes. It's the entire claim. So it's the  
15 entire claim paid by TRICARE.

16          Now, I think you're right that this discussion will  
17 obviously go on throughout this case. There will be  
18 discovery. There will be experts. There may be some sort of  
19 discount on, you know, perhaps an expert will opine what a  
20 reasonable discount would be between the AWP and the  
21 acquisition price, and damages may end up at the end of the  
22 day not being the entirety of the claim, but at this point I  
23 think it's premature.

24          THE COURT: Yeah. No. So we are here on just the  
25 motion to dismiss, but I just, in the event that the motion to

1 dismiss fails and this case continues, while you're all here  
2 on the line, I wanted to raise that subject.

3 And so while we're still all on the line, under the  
4 assumption -- this isn't a ruling yet, I'm going to take this  
5 under advisement, but under the assumption that the motion to  
6 dismiss is denied, how do we go forward on discovery from the  
7 government/relator standpoint?

8 MR. DECK: I'm going to let my colleague,  
9 Mr. Bhambhani address discovery.

10 THE COURT: Counsel.

11 I don't see Mr. Bhambhani on the line.

12 MR. BHAMBHANI: I'm trying to unmute.

13 MR. GROSSENBACHER: There you go.

14 THE COURT: There you are.

15 MR. BHAMBHANI: Okay. Is that better? Can you hear  
16 me, Your Honor?

17 THE COURT: Yes, I can. Thank you.

18 MR. BHAMBHANI: Good morning, Your Honor. This is  
19 Sanjay Bhambhani from the Department of Justice.

20 Just to clarify a point that Mr. Deck made, the  
21 billion dollars reference, the total amount that TRICARE paid  
22 for all of PCCA's ingredients, what we've alleged in the  
23 complaint, and we focused our complaint on ten ingredients,  
24 and we focused on two of those ingredients, Fluticasone and  
25 Resveratrol, but that's the total amount that TRICARE ended up

1 paying. It goes to essentially refute the notion that the  
2 government did not -- or TRICARE did not pay for these  
3 ingredients. It paid a lot of money.

4 In terms of where we go from here, Your Honor, Your  
5 Honor did ask for a revised scheduling order. We have had  
6 discussions with PCCA. We've submitted that revised  
7 scheduling order. I think we've agreed in terms of the number  
8 of depositions, that we are on 30 each, at least that's what  
9 we've proposed.

10 There are certain lines of inquiry that we've laid  
11 out as to what the government thinks it needs in terms of  
12 discovery, and also the defendants of PCCA has also identified  
13 what it claims it needs for its discovery. And so I think  
14 we're prepared to go forward.

15 We have proposed initial disclosures for July 1st,  
16 and so we're ready to proceed on the assumption that the Court  
17 denies the motion to dismiss.

18 THE COURT: One second. Let me go to my docket  
19 sheet. So, yes, I see on June 10th I received a proposed  
20 scheduling order and so we have not entered that. We need to  
21 do so.

22 MR. BHAMBHANI: That is correct.

23 THE COURT: And that proposed scheduling order is  
24 agreed to by PCCA, is that correct?

25 MR. BURBA: Your Honor, based on Your Honor's minute

1 order, we are agreeing with this schedule now.

2 We did want to raise for the Court the point that,  
3 you know, under the False Claims Act the government has  
4 immense investigatory powers and used those for a period of  
5 about eight years in this case.

6 The majority of the discovery we expect to take will  
7 likely require *Touhy* requests and cooperation from the  
8 government, and so we are concerned that the shorter discovery  
9 period may not allow us to sufficiently go through that  
10 process, depose the witnesses we need to depose, and request  
11 and receive the documents that we are going to need.

12 I don't know that we have any relief we'd request  
13 from the Court at this point other than to ask that the Court  
14 keep an open mind and just recognize that in the event that  
15 discovery does slow down, you know, out of just fairness,  
16 given the government's eight-year investigation, we think  
17 reasonable extensions of discovery may be necessary.

18 THE COURT: No, that's understood.

19 Now, to the government, I mean, you-all have been  
20 investigating for quite a period of time. I mean, I don't see  
21 why there's any reason why you can't turn over most of your  
22 documents in some kind of a format that you-all can agree to  
23 for any discovery platform to review. I'm sure it's going to  
24 be voluminous, and so I can't understand why there would be a  
25 problem by the government production.

1           And then with regard to witnesses, Mr. Deck, or I'm  
2 not sure who is in charge of that, witnesses, do we have to  
3 actually go through the *Touhy* framework? I mean, you know who  
4 the individuals are that you need to present.

5           Who wants to respond to that? Mr. Bhambhani or  
6 Mr. Deck?

7           MR. BHAMBHANI: Your Honor, as to whether or not  
8 *Touhy* applies, it's my understanding, but I need to confirm  
9 this, that *Touhy* applies when the government is a nonparty,  
10 but --

11          THE COURT: Well, you're not quite a nonparty here.  
12 You are a beneficiary.

13          MR. BHAMBHANI: No, no. That's right. So I'm not  
14 sure that the *Touhy* process is necessarily -- is necessary,  
15 because the government obviously is a party in this case.

16          And, of course, we will make every effort to try to  
17 comply with the discovery request here. I mean, that goes  
18 without saying, Your Honor. We'll make every effort to  
19 cooperate, of course, reserving our right to object to what we  
20 consider to be unreasonable requests that might be overbroad,  
21 unduly burdensome, et cetera.

22          THE COURT: So I understand that, but when we are  
23 talking about a billion dollars too and the proportionality  
24 analysis, that's quite a large amount in controversy.

25          MR. BHAMBHANI: Again, Your Honor, I do want to make

1 clear, that is not what we are claiming as the amount of  
2 damages.

3 That was the amount that TRICARE ended up paying, and  
4 we're focusing on a much narrower subset of claims. And we're  
5 focusing on -- and that's what we've tried to do in our  
6 complaint, focusing on the ten ingredients that had the most  
7 egregious AWP spreads. So we're not going after every single  
8 item or claim.

9 And we've also identified, in terms of the examples,  
10 claims that were between \$2,000 and above. It's not every  
11 ingredient.

12 THE COURT: Yeah. So let's try to -- if that's going  
13 to be your contention here how you are going forward, let's  
14 just make that clear so discovery is limited to those issues.  
15 And then while you-all are talking we all know what to focus  
16 in on the numbers regarding those issues.

17 I'll just wait for the inevitable discovery fights.  
18 Hopefully, they will be minimal. And if you-all -- either  
19 side needs more time, I'm willing to work with you on a  
20 scheduling order, but this is an old case, so we're going to  
21 move it forward.

22 Anything else from the government/relators?

23 MR. DECK: No, I don't think so.

24 THE COURT: Thank you.

25 Anything else from PCCA?

1 MR. BURBA: Your Honor, I know that we're proceeding  
2 under an assumption related to the motion to dismiss. I would  
3 beg the Court's indulgence to address just a few of the points  
4 that Mr. Deck made and also ask a question about a point that  
5 Mr. Bhambhani just made.

6 THE COURT: Sure. Go ahead.

7 MR. BURBA: So first is the government's position  
8 then that they are limiting their claim for damages to the ten  
9 ingredients listed in the complaint?

10 THE COURT: That's a good question, because is it ten  
11 or two?

12 Who wants to answer?

13 MR. BHAMBHANI: Your Honor, we focused on the ten  
14 ingredients. We've identified ten ingredients, and those  
15 ingredients themselves involve — would produce overpayments  
16 of, you know, over \$100 million.

17 Now, Your Honor, again, we're not talking about every  
18 single ingredient but we are willing to focus our complaint  
19 and we have limited our complaint to the ten ingredients.

20 And I'd also like to add, Your Honor, this case is a  
21 TRICARE case. It's not Medicare, Medicaid, VA, or anything  
22 like that. We have limited our case to TRICARE. And I just  
23 want to make that point very clear.

24 THE COURT: Thank you. So ten ingredients, TRICARE.

25 What else do you got, Mr. Burba?

1 MR. BURBA: Well, I would note for Your Honor that  
2 the reason it's only a TRICARE case is that Medicare and other  
3 federal health programs took action upon the adoption of  
4 Didado [phonetic] to avoid this exact issue, because it was  
5 known to the government, but --

6 THE COURT: Let me stop you there. So, you know, I  
7 understand that point, but right now, procedurally, I'm just  
8 dealing with a motion to dismiss. So you may or may not have  
9 a point on other issues for summary judgment, but I'm just  
10 dealing with a motion to dismiss.

11 MR. BURBA: Understood.

12 And in that vein, Your Honor, I would say two points  
13 are worth making. The first is that -- I'm sorry, three  
14 points in response to the three points Mr. Deck made.

15 The first is the allegation that we knew that the  
16 customers were submitting claims, I'm not sure that that's  
17 really relevant to the argument that we've made in our motion  
18 to dismiss.

19 I mean, even if our client is assumed to have known  
20 the TRICARE claims were being submitted, there was no guidance  
21 in the market as to how they should set their AWP. The  
22 exhibits to the complaint, which I'm sure Your Honor has  
23 reviewed, show that at least, according to those emails, PCCA  
24 thought that the conduct was legal because there had been no  
25 guidance or effort from the government to give clarity.



1 THE COURT: Well, Mr. Burba, let me stop you there.  
2 I mean, isn't there some kind of reasonableness  
3 standard that applies here? I mean, a thousand percent charge  
4 markup?

5 MR. BURBA: Well, but I think, that's only if you --  
6 I mean, if Your Honor looks to the acquisition cost as the  
7 government suggests, then that may be the case, but I don't  
8 think the government has given Your Honor any legal basis for  
9 that.

10 In fact, if you look at the First Circuit case and  
11 the *In Re* case from Mississippi, one of the key differences in  
12 those cases was that AWP was not the actual measure being used  
13 by the government. It was estimated acquisition cost for  
14 which AWP was standing in.

15 And so those courts were looking at this in a very  
16 different setting, where, you know, estimated acquisition  
17 costs was really the term that they were looking at, and so it  
18 made more sense.

19 Here, there was no such guidance by TRICARE, despite  
20 the fact that as the testimony we submitted as Exhibit B  
21 shows, they knew that this was an undefined term allowing for  
22 manufacturers to set AWP at whatever they wanted as far back  
23 as 2002.

24 But we would take the position that if you review the  
25 exhibits, which the Court is allowed to do, and interpret on

1 its own in a motion to dismiss because they are the documents  
2 the government attached, what you ultimately see is that the  
3 standard by which we set our AWP's was our competitors, and  
4 what we saw going on in the market, which we believe is  
5 reasonable commercial activity in the absence of any other  
6 guidance by the government.

7 Now, the government has pointed to a settlement by  
8 one of our competitors, but that was well after the events  
9 that occurred here. It was a no-fault settlement, no  
10 liability acknowledged. So it's not clear why that would be  
11 relevant to the time that we were operating in.

12 We were a commercial actor who did no business with  
13 the government, who were selling to customers who had a direct  
14 relationship with the government, and were responding to  
15 market factors that were created by the knowing conduct of the  
16 government, and we don't believe that the government should  
17 get the benefit of the doubt, or a pass, on the fact that it  
18 created the environment in which these AWP's were determined.

19 THE COURT: But what you are neglecting to say,  
20 though, and what's alleged in the complaint, is that your  
21 client was telling these pharmacies, "Don't tell TRICARE the  
22 real price that you guys are paying, and if they ask, talk to  
23 us first," and so you are omitting all of that from the  
24 allegations.

25 MR. BURBA: Well, and I would point out, if you look

1 at those Zaccarrian [verbatim] emails, I don't think that's  
2 what they say, because what they say is the government was  
3 already receiving -- and I'm not looking at it right now but I  
4 know that this is generally what they say -- what they say is  
5 that the government is receiving the invoices as part of the  
6 claim, but which contains the information the government has  
7 pleaded that they were required to submit which included  
8 pricing information and the acquisition cost.

9 And then there was another document which I believe  
10 was the claim where the AWP was listed.

11 But I mean, while those documents suggest that we  
12 were telling them not to put the two numbers next to each  
13 other, they also show clearly that the two numbers were still  
14 going to the government with the claims.

15 I would also point out, if you look at the GAO  
16 report, the GAO report indicates that TRICARE was running its  
17 own medical facilities and that those medical facilities were  
18 purchasing these ingredients for use in compound medications.

19 So TRICARE was a customer of either PCCA or one of  
20 its competitors and was well aware, as a customer, of what the  
21 acquisition costs were. And this is not asking the Court to  
22 assume facts outside the complaint. This is asking the Court  
23 to look at the record in front of it, which the government has  
24 not objected to the Court looking at --

25 THE COURT: But aren't you asking me to make fact

1 determinations at this pleading stage? I mean, it seems like  
2 you are making motion for summary judgment arguments.

3 MR. BURBA: With all due respect, Your Honor, I don't  
4 believe that I am.

5 I mean, you are required to consider the government's  
6 allegations as true, and you are required to give them fair  
7 inferences, but I don't think fair inferences involve or  
8 prohibit the Court from looking at inconsistencies between the  
9 allegations made in the complaint and questioning whether  
10 those inconsistencies and apparent, you know, factual --  
11 factually incorrect information based on the GAO report is  
12 false.

13 You know, I would note the government has not  
14 objected to the Court considering those GAO reports and  
15 actually argued that the Court use them in support of its  
16 argument. They are the government's own document prepared at  
17 the direction of Congress. So I think those are perfectly  
18 appropriate for the Court to consider in evaluating the  
19 reasonableness of the allegations.

20 You know, I would point to one final factor, which is  
21 the Court is required to give credence to and draw inferences  
22 for the government, but, you know, the government investigated  
23 this case for eight years. Like eight years.

24 And they had eight years to write this complaint and  
25 come up with their best -- put their best foot forward for the

1 Court. And they submitted an exhibit, Exhibit 28, that has  
2 eight clear errors showing that claims were paid in 1900.

3 Now, we have not been given the TRICARE data relevant  
4 here, but it draws into question for us the accuracy of the  
5 government's information.

6 I understand that sounds like a summary judgment  
7 argument, but my point here is if the government attaches the  
8 documents, the Court can rely on the documents and a fair  
9 interpretation of those documents at the summary -- I'm  
10 sorry -- at the motion to dismiss stage, and that's what we're  
11 asking the Court to do.

12 THE COURT: Thank you.

13 I'll take the motion to dismiss under advisement. I  
14 could very well change my mind, and this is not a ruling, but  
15 you-all ought to act under the assumption this case is going  
16 forward.

17 To me, a lot of this seems to be disputed fact issues  
18 that are appropriate for a summary judgment, but I'm keeping  
19 an open mind. I'm going to revisit the motion to dismiss in  
20 light of the arguments and I'll try to get an order out as  
21 soon as I can.

22 Anything else from the government/relators that we  
23 need to take up today?

24 MR. DECK: No, Your Honor.

25 THE COURT: Anything else from the defendant?

1 MR. BURBA: No, Your Honor. And thank you for your  
2 time and attention today.

3 THE COURT: Thank you.

4 We're in recess until 1:30.

5 *(Concludes proceedings)*

6 -o0o-

7 I certify that the foregoing is a correct transcript from  
8 the record of proceedings in the above-entitled matter. I  
9 further certify that the transcript fees and format comply  
10 with those prescribed by the Court and the Judicial Conference  
11 of the United States.

12  
13 Date: 07/19/22

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